Supreme Court, U.S.
FILED
OCT 18 1985
JOSEPH F. SPANIOL, JR.
CLERK

No. 85-664

# In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

*v.*

COMMUNITY NUTRITION INSTITUTE, ET AL.

## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

CHARLES FRIED
*Acting Solicitor General*
RICHARD K. WILLARD
*Acting Assistant Attorney General*
KENNETH S. GELLER
*Deputy Solicitor General*
SAMUEL A. ALITO, JR.
*Assistant to the Solicitor General*
LEONARD SCHAITMAN
MARLEIGH D. DOVER
*Attorneys*

*Department of Justice*
*Washington, D.C. 20530*
*(202) 633-2217*

THOMAS SCARLETT
*Chief Counsel*
*Food and Drug Administration*
*Rockville, Maryland 20857*

BEST AVAILABLE COPY

## QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable "added" poisonous or deleterious substances in food by means of formal rulemaking pursuant to 21 U.S.C. 342(a)(2)(A), rather than by case-by-case adjudication pursuant to 21 U.S.C. 342(a)(1).

## PARTIES TO THE PROCEEDING

The petitioner is Frank Young, Commissioner of Food and Drugs. The respondents are the Community Nutrition Institute, Public Citizen, and Linda S. Bardot.

## TABLE OF CONTENTS


| | Page |
|---|---|
| Opinions below | 1 |
| Jurisdiction | 1 |
| Statutory and regulatory provisions involved | 2 |
| Statement | 2 |
| Reasons for granting the petition | 7 |
| Conclusion | 18 |
| Appendix A | 1a |
| Appendix B | 17a |
| Appendix C | 18a |
| Appendix D | 19a |
| Appendix E | 20a |
| Appendix F | 35a |
| Appendix G | 36a |


## TABLE OF AUTHORITIES

Cases:


| | |
|---|---|
| *Chemehuevi Tribe of Indians* v. *FPC*, 420 U.S. 395 | 11 |
| *Chemical Manufacturers Ass'n* v. *NRDC*, No. 83-1013 (Feb. 27, 1985) | 7, 8 |
| *Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 25, 1984) | 8 |
| *Dickerson* v. *New Banner Institute, Inc.*, 460 U.S. 103 | 9 |
| *Haig* v. *Agee*, 453 U.S. 280 | 11 |
| *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985) | 18 |
| *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267 | 10 |
| *NLRB* v. *Gullett Gin Co.*, 340 U.S. 361 | 11 |
| *Pattern Makers* v. *NLRB*, No. 83-1894 (June 27, 1985) | 8 |
| *Train* v. *NRDC*, 421 U.S. 60 | 8 |
| *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151, aff'd, 622 F.2d 157 | 13 |
| *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149 | 13, 14, 15 |
| *United States* v. *Goodman*, 486 F.2d 847 | 14, 15 |
| *United States* v. *Rutherford*, 442 U.S. 544 | 8 |

Statute and regulations: Page

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*:

§ 301, 21 U.S.C. 331 ..... 2, 17
§ 302, 21 U.S.C. 332 ..... 17
§ 303, 21 U.S.C. 333 ..... 17
§ 304, 21 U.S.C. 334 ..... 17
§ 306, 21 U.S.C. 336 ..... 18
§ 402, 21 U.S.C. 342 ..... 2, 11
§ 402(a), 21 U.S.C. 342(a) ..... 2, 36a
§ 402(a)(1), 21 U.S.C. 342(a)(1) ..... 2, 3, 7, 9, 10, 11, 12, 17
§ 402(a)(2), 21 U.S.C. 342(a)(2) ..... 9, 10, 16
§ 402(a)(2)(A), 21 U.S.C. 342(a)(2)(A) ..... 2, 3, 10
§ 406, 21 U.S.C. 346 ..... *passim*
§ 408, 21 U.S.C. 346a ..... 11, 15
§ 408(b), 21 U.S.C. 346a(b) ..... 14
§ 701, 21 U.S.C. 371 ..... 15
§ 701(e), 21 U.S.C. 371(e) ..... 2, 4, 38a
§ 701(e)(2), 21 U.S.C. 371(e)(2) ..... 4
§ 701(e)(3), 21 U.S.C. 371(e)(3) ..... 4
§ 701(f), 21 U.S.C. 371(f) ..... 4

5 U.S.C. 703 ..... 15

21 C.F.R.:

Pt. 109 ..... 4
Pt. 509 ..... 5
Section 509.6(b)-(c) ..... 2, 5, 40a
Section 509.6(b)(3) ..... 16

Miscellaneous:

*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. (1953) ..... 11

*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 2d Sess. (1954) ..... 11

27 Fed. Reg. 5705 (1972) ..... 16

38 Fed. Reg. 18096 (1973) ..... 16

40 Fed. Reg. 11563 (1973) ..... 16



Miscellaneous – Continued: Page

42 Fed. Reg. (1977):

p. 14487 ..... 17
p. 52817 ..... 4

44 Fed. Reg. 38330 (1979) ..... 17

47 Fed. Reg. 10079 (1982) ..... 17

48 Fed. Reg. 37020 (1983) ..... 16

49 Fed. Reg. 21514 (1984) ..... 17

H.R. Rep. 1385, 83d Cong., 2d Sess. (1954) ..... 12, 16

*Residues of Pesticide Chemicals: Hearing on S. 2868 and H.R. 7125 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 83d Cong., 2d Sess. (1954) ..... 12

S. Rep. 1635, 83d Cong., 2d Sess. (1954) ..... 12, 15

# In the Supreme Court of the United States

OCTOBER TERM, 1985

No.

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

*v.*

COMMUNITY NUTRITION INSTITUTE, ET AL.

## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Solicitor General, on behalf of the Commissioner of Food and Drugs, petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

### OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-16a) is reported at 757 F.2d 354. The May 1, 1985 order amending the court of appeals' opinion (App., *infra*, 17a) and the opinion of the district court (App., *infra*, 21a-34a) are unreported.

### JURISDICTION

The judgment of the court of appeals (App., *infra*, 35a) was entered on March 26, 1985. A petition for rehearing was denied on May 23, 1985 (App., *infra*, 18a). By order dated August 13, 1985, Justice Brennan extended the time within which to file a petition for a writ of certiorari to and including October 20, 1985. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATUTORY AND REGULATORY PROVISIONS INVOLVED

Sections 402(a), 406, and 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), 346, and 371(e), and 21 C.F.R. 509.6(b)-(c) are reproduced at App., *infra,* 36a-40a.

## STATEMENT

This case concerns the procedures that the Food and Drug Administration (FDA) must employ in regulating the presence in food of any added poisonous or deleterious substance that is required in the production of the food or that cannot be avoided by good manufacturing practice. The specific substance at issue here is "aflatoxin," a carcinogenic mold byproduct that commonly grows on corn and other crops. Since the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938, the FDA has regulated the amounts of substances like aflatoxin principally by issuing what the FDA terms "action levels." These "action levels" announce the level of the particular substance that the FDA regards as resulting in adulteration under 21 U.S.C. 342(a)(1). In this case, the court of appeals upset this longstanding administrative interpretation of the FDCA and held that the FDA must instead set tolerances by time-consuming and burdensome formal rulemaking procedures.

1. *Statutory and Regulatory Scheme.* The FDCA, 21 U.S.C. 331, prohibits the shipment in interstate commerce of "adulterated" food. Under 21 U.S.C. 342, a food is deemed to be adulterated if either of two conditions is met. The first, Section 342(a)(1), applies to all poisonous substances, whether inherent in the food or "added" to it, and provides that a food is adulterated if it contains "any poisonous or deleterious substance which may render it injurious to health." The second, Section 342(a)(2)(A), applies only to "added" poisons and states that food is adulterated if it contains any "added poisonous or added deleterious substance * * * which is unsafe within the



meaning of" 21 U.S.C. 346. Aflatoxin is regarded as an added poison because it is added by mold, *i.e.*, it is not an inherent constituent of food.

Section 346 defines when a food with an added poison is "unsafe" within the meaning of that provision. The first clause of Section 346 provides that any added poison renders the food unsafe unless its presence "is required in the production thereof or cannot be avoided by good manufacturing practice * * *." Since aflatoxin falls within this exception, food containing aflatoxin is not rendered "unsafe" by this clause. Section 346 next addresses the question of when a food to which a required or unavoidable poison, like aflatoxin, has been added is deemed to be unsafe. The statute provides in pertinent part:

> [W]hen such substance is so required or cannot be so avoided, the Secretary [of Health and Human Services] shall promulgate regulations limiting the quantity therein or thereon to such entent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of [Section 342(a)(2)(A)].

For nearly a half-century, the FDA has interpreted these provisions as allowing it to regulate substances such as aflatoxin either by structuring its discretion to bring enforcement actions under Section 342(a)(1) or by issuing formal regulations pursuant to Sections 342(a)(2)(A) and 346. If the FDA elects to proceed under Section 342(a)(1), the government must establish in an enforcement proceeding that the level of the substance present may render the food injurious to health. This is the option that the FDA has used with respect to aflatoxin, and the FDA has adopted an action level to aid the agency in the exercise of

---

[1] Since 1969, the action level for aflatoxin in human food or animal feed has been 20 parts per billion. App., *infra,* 22a.

its prosecutorial discretion.[1] In the alternative, FDA may promulgate a Section 346 tolerance. Once a tolerance is in effect, the government in an enforcement proceeding need only establish that the tolerance has been violated; it need not adduce independent evidence that the food may be injurious to health. See 21 U.S.C. 346.

The procedures employed in promulgating action levels differ significantly from those required for issuance of tolerances. Action levels are not subject to notice-and-comment rulemaking under the Administrative Procedure Act. However, the FDA does publish a notice in the *Federal Register* announcing the new level and the availability of all the relevant data, and it invites public comment. 42 Fed. Reg. 52817 (1977). By contrast, 21 U.S.C. 371(e) prescribes a formal and complicated procedure for the issuance of regulations setting tolerances under Section 346. Within 30 days after publication of a final regulation in the *Federal Register,* any party who may be adversely affected may file objections and request a public hearing. 21 U.S.C. 371(e)(2). The filing of such objections stays the effectiveness of the proposed regulation until the Secretary of Health and Human Services takes final action on the objections. *Ibid.* If the objections raise genuine and substantial factual issues, the Secretary, after providing further notice in the *Federal Register,* must conduct a public hearing at which "any interested person may be heard in person or by representative." 21 U.S.C. 371(e)(3). The Secretary must then rule on the objections, setting forth "detailed findings of fact." *Ibid.* Except in emergencies, the regulation may not take effect until 90 days after the Secretary's decision (*ibid.*), which is subject to judicial review (21 U.S.C. 371(f)).

In determining whether to issue informal action levels or formal tolerances in a particular case, the FDA takes these procedural differences into account. FDA regulations provide for the use of action levels when it is impracticable to



set tolerances. See 21 C.F.R. Pt. 109 (human food); 21 C.F.R. Pt. 509 (animal food). For example, action levels rather than tolerances are to be used when changes in the capabilities of good manufacturing practices are expected or when the results of ongoing studies might provide significant new toxicological data or other data that might render a tolerance obsolete. 21 C.F.R. 509.6(b)-(c).

2. *Proceedings Below.* Respondents (two public interest groups and a consumer) brought this suit in the United States District Court for the District of Columbia to challenge the FDA's regulation of aflatoxin. Respondents contended (1) that the FDA should be compelled to adopt a formal aflatoxin tolerance pursuant to Section 346, as opposed to an informally implemented action level (2) that the action level, in the alternative, should be made subject to notice-and-comment rulemaking, and (3) that certain exemptions to the action level were contrary to law. The district court granted summary judgment in favor of the FDA on all three issues. Recognizing that an agency's interpretation of its statute is entitled to substantial deference, the court found that the FDA's construction of Section 346 was reasonable and that Section 346 "confers discretionary, not mandatory, authority on the agency to establish tolerances." App., *infra,* 31a-32a (footnote omitted). It also concluded that "action levels" were general statements of policy not requiring notice-and-comment rulemaking and that the exemptions granted were within the agency's discretion. *Id.* at 32a-34a.

The court of appeals reversed, holding that "the FDA may not proceed by means of action levels rather than tolerances" (App., *infra,* 2a).[2] In reaching this conclusion, the court relied heavily on its parsing of the second

---

[2] Because the court of appeals reversed on this ground, it did not consider respondents' other claims (App., *infra,* 2a).

sentence of Section 346, which, as noted, provides that when an added poisonous or deleterious substance is "required" or "cannot be * * * avoided"

> the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health.

The court refused to accept (App., *infra,* 6a) the FDA's interpretation of this provision, *i.e.,* that the Secretary is obligated to promulgate formal regulations only " 'to such extent as [he] finds necessary for the protection of public health' " and may employ informal action levels in all other circumstances. Instead, the court found (*id.* at 7a) that it was "clear from the structure of the sentence * * * that the phrase relied upon by the Secretary simply does not modify the pivotal word 'shall' " but, rather, "explains the standard that the Secretary is to employ in setting the tolerance."

The court of appeals found additional support for its interpretation in an argument that seems to suggest that much of the nation's food supply is "adulterated" within the meaning of the FDCA. The court interpreted (App., *infra,* 7a) Section 346 to mean that any food to which an unavoidable poisonous or deleterious substance has been added is adulterated unless "a regulation establishing a tolerance is in effect." The court reasoned (App., *infra,* 7a):

> Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce.

The court of appeals advanced no other arguments to buttress its interpretation. It found "little guidance in the legislative history" (App., *infra,* 9a), and it did not cite any supporting judicial authority, but instead merely attempted to distinguish the cases upon which the FDA relied (*id.* at 11a-15a).



## REASONS FOR GRANTING THE PETITION

In the production of food, it is often impossible to avoid the presence of small quantities of added substances that may be harmful to human health if taken in sufficient amount. For nearly 50 years, the FDA has regulated the presence of such substances in food principally by issuing informal "action levels" and by enforcing these standards through litigation under Section 342(a)(1) of the FDCA. This informal procedure has allowed the FDA to move quickly in response to health hazards; it has provided flexibility in an area in which the relevant scientific data and the capabilities of good manufacturing processes are subject to frequent changes; and it has permitted the FDA, by limiting burdensome and unproductive formal rulemaking proceedings, to allocate its scarce resources to activities of greater value in safeguarding the public health.

The court of appeals' decision, which upsets this settled and successful practice, threatens to squander administrative resources and to impair the FDA's ability to act expeditiously and respond to changed conditions in this important area. The court's reasoning also suggests that much of the nation's food supply is now and will remain "adulterated" within the meaning of the FDCA until formal regulations setting tolerances are issued—a process that is certain to take years, if not decades, to complete. For these reasons, this case concerns a matter of substantial importance that warrants this Court's review.

1. a. An agency's interpretation of the statute it is charged with administering is "entitled to considerable deference." *Chemical Manufacturers Ass'n* v. *NRDC,* No. 83-1013 (Feb. 27, 1985), slip op. 8. "[T]o sustain it, [a court] need not find that it is the only permissible construction that [the agency] might have adopted but only that [the agency's] understanding * * * is a sufficiently rational one to preclude a court from substituting its judgment for that of [the agency]." *Id.* at 8-9. See also

*Chevron U.S.A. Inc.* v. *NRDC,* No. 82-1005 (June 25, 1984), slip op. 4-7; *United States* v. *Rutherford,* 442 U.S. 544, 553-554 (1979); *Train* v. *NRDC,* 421 U.S. 60, 75 (1975). Under this standard, the FDA's interpretation of the relevant provisions of the FDCA should have been sustained.

As the court of appeals recognized, the pivotal statutory provision is the second sentence of 21 U.S.C. 346, which provides that when any added poisonous or deleterious substance is "required" in the production of food or "cannot be avoided by good manufacturing practice,"

> the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health * * *.

In the FDA's view, the phrase "to such extent as he finds necessary for the protection of public health" modifies the verb "shall." Accordingly, the FDA has consistently interpreted this provision to mean that it must promulgate regulations only if it finds that they are necessary for the protection of public health.

The court of appeals, by contrast, concluded that the critical phrase "to such extent as he finds necessary for the protection of public health" modifies the participle "limiting." Thus, in the court's view, the FDA must promulgate regulations establishing tolerances for *all* added poisonous or deleterious substances that cannot practicably be avoided in food production, and these regulations must "limit[ ] the quantity" of such substances "to such extent as [the FDA] finds necessary for the protection of public health."

Both interpretations of the statutory language are entirely rational and plausible. Therefore, the statutory language provides no basis for overriding the FDA's longstanding construction of the statute it has been entrusted by Congress with administering, especially in view of the statute's complexity. See *Pattern Makers* v. *NLRB*, No. 83-1894 (June 27, 1985), slip op. 19; *Chemical Manufacturers Ass'n*, slip op. 8. Even if the court of appeals believed that its own interpretation of the statutory language corresponded with the most refined rules regarding the proper placement of modifiers, that alone was not a sufficient reason for refusing to defer to the FDA's interpretation. After all, complex regulatory statutes like the FDCA often appear to be written in a language that is all their own, and thus adherence to the highest standards of normal usage is not always a reliable way to divine Congress's intent.



b. Not only is the language of Section 342(a)(1) insufficient to support the court of appeals' interpretation, but that interpretation is critically undermined by the overall structure of the statutory scheme. It is a cardinal rule of statutory interpretation that a statute should be construed so as to give effect to all of its provisions. See, *e.g.*, *Dickerson* v. *New Banner Institute, Inc.*, 460 U.S. 103, 118 (1983). Here, FDA's construction satisfies this canon, while the court of appeals' interpretation makes Section 342 (a)(1) superfluous for "added" substances, like aflatoxin, even though Section 342(a)(1) was expressly intended to play a role in the regulation of such substances.[3]

Under Section 346, the addition of a poisonous or deleterious substance automatically renders a food "unsafe" (and thus "adulterated" under Section 342(a)(2)) unless the added substance is "required" or cannot practicably be avoided. Thus, it is undisputed that Section 342(a)(1) is not needed to regulate substances that are not required or are avoidable in food production. This obviously leaves only those added substances that are required or cannot practicably be avoided. As previously noted, FDA's view is that it may regulate the occurrence of these substances either by issuing action levels and bring-

[3] Section 342(a)(1) states that "*in case the substance is not an added substance* such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health" (emphasis added). This sentence makes clear that Section 342(a)(1) was meant to govern both added and inherent substances.

ing suit in appropriate cases under Section 342(a)(1) (in which case the FDA must prove in court that the added substance renders the food "injurious to health") or by promulgating formal regulations under Section 346 (in which case any food exceeding those tolerances is automatically deemed to be unsafe and adulterated). Cf. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). This interpretation assigns an important role to both Section 342(a)(1) and Section 342(a)(2).

Under the court of appeals' interpretation, however, FDA must issue formal regulations for all such substances. Once such regulations are promulgated, Section 342(a)(1) has no role to play. If a food is "unsafe" under Section 342(a)(2)(A) by virtue of a formal regulation, FDA would have no need to proceed under Section 342(a)(1), which requires proof in court of injury to health. And if a food is deemed to be "safe" under such a regulation, Section 346 expressly provides that the food "shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated" under Section 342(a)(1).[4]

c. The language and structure of the FDCA thus provide substantial support for the FDA's long-settled construction of the statute. Indeed, the FDA's interpretation is entitled to enhanced deference because Congress has specifi-

[4] Besides its parsing of the second sentence of Section 346, the court of appeals' only ground for its decision was the belief that a food containing a substance such as aflatoxin is adulterated and thus cannot be shipped in interstate commerce unless a regulation establishing a tolerance is in effect. App., *infra*, 7a. This interpretation of the statute is mistaken. To be sure, if a tolerance has been set, a food containing a substance such as aflatoxin is unsafe and adulterated under Sections 342(a)(2) and 346 unless the tolerance is met. But neither these nor any other provisions of the FDCA provide that a food containing a substance like aflatoxin is unsafe or adulterated if no tolerance is in effect. In that situation, Sections 342(a)(2) and 346 are silent. Section 342(a)(1) is then the governing provision, and the food is considered to be adulterated only if it can be shown to be "injurious to health."



cally noted that interpretation while considering revisions of the FDCA but has done nothing to alter the administrative practice. See *Haig* v. *Agee*, 453 U.S. 280, 297-298 (1981); *Chemehuevi Tribe of Indians* v. *FPC*, 420 U.S. 395, 410 (1975); *NLRB* v. *Gullett Gin Co.*, 340 U.S. 361, 366 (1951).

Under the FDCA, pesticide residues in food were originally governed by Section 346, but in 1954 Congress enacted a new provision, 21 U.S.C. 346a, to regulate the presence of pesticide residues in raw agricultural products. During the hearings preceding passage of this legislation, both the Commissioner of Food and Drugs and industry representatives called the FDA's position to Congress's attention,[5] and this interpretation not only was expressly

[5] The FDA Commissioner, Charles W. Crawford, stated (*Federal Food Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 121 (1953):

> We have given out so-called informal tolerances on a great many of these things, we have freely given that out and if their schedules bring those spray residues within those informal tolerances there is no basis under the law for us to proceed because if we proceed on the other provision of section 402 [21 U.S.C. 342]—that is 402(a)(1) [21 U.S.C. 342(a)(1)], we have to assume the burden of proving that the quantity of the spray residue present in this particular commodity here in and of itself may injure the health of consumers and we would not give a tentative tolerance at a figure where there was any likelihood of our being able to make a case of that kind.

The National Canners Association wrote to both the House and Senate committees to express its understanding that Section 408 (21 U.S.C. 346a) would apply only to raw agricultural products. The Association's letter to the House committee stated (*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 2d Sess. 31 (1954) (emphasis added)):

> It is the understanding of the National Canners Association that after passage of this bill processed foods will be in exactly the same position as before in that *tolerances for pesticide residues*

noted by both the House and Senate committees but appears to have played an important part in their thinking. See H.R. Rep. 1385, 83d Cong., 2d Sess. 2, 6-7 (1954); S. Rep. 1635, 83d Cong., 2d Sess. 6 (1954). The House Report observed that while the law "authorizing" the issuance of formal tolerances had been in effect for more than 15 years, "[d]uring all that time control has been exercised through unofficial and informal tolerances." H.R. Rep. 1385, *supra,* at 2. The Report continued (*id.* at 2-3) that in 1950 "lengthy public hearings," costing nearly $500,000, had been held for the purpose of establishing official tolerances for pesticide residues in fresh fruits and vegetables but that official tolerances still had not been promulgated due to "the cumbersome, time-consuming, and impracticable procedure prescribed by existing law." To overcome these difficulties, the House committee recommended (*id.* at 2) "an improved procedure for establishment of tolerances for pesticide chemicals remaining in or on raw agricultural commodities." The Senate Report (S. Rep. 1635, *supra,* at 6) made the identical points.

Thus, the congressional committees expressly observed that the FDA was relying chiefly on informal rather than formal tolerances, yet they did not suggest that this practice was unlawful or undesirable and did nothing to require its abandonment in favor of exclusive reliance on formal rulemaking. On the contrary, the committees sharply criticized the formal statutory procedure set out in the FDCA Act and crafted a new, simpler, and speedier method for rectifying the problem caused by the breakdown of the formal procedure in the field of pesticide residues on raw agricultural products. This is powerful evidence that Congress approved the FDA's interpretation of the statutory provisions at issue here.

2. The court of appeals' interpretation of these provisions is inconsistent with that of the Fifth Circuit in *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149 (1979), an action to enjoin shipment of grain containing an amount of aflatoxin exceeding the FDA's action level. There, the Fifth Circuit expressly adopted the interpretation of the relevant statutory provisions that the D.C. Circuit rejected in this case. The Fifth Circuit wrote (*id.* at 151):

> In implementing the Act, the FDA either may adopt formal regulations, 21 U.S.C. § 346, or may litigate alleged violations on a case-by-case basis. * * * To guide its prosecutorial discretion in the bringing of non-rule enforcements of the Act the FDA may establish certain in-house guidelines called action levels.

Holding that the grain at issue was adulterated, the court noted (*ibid.*) that it had "evolved a policy of considerable deference to agency action levels." See also *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1153 n.2 (N.D. Fla. 1978), aff'd, 622 F.2d 157 (5th Cir. 1980).

The D.C. Circuit in the present case distinguished *Boston Farm Center* (App., *infra,* 11a-12a) on the ground that it concerned the FDA's authority to enjoin shipment of adulterated grain without issuing a formal tolerance and did not address the FDA's obligation to issue a formal tolerance. This is an exceedingly narrow distinction that

---

*with respect to processed foods may be established under section 406 [21 U.S.C. 346] of the Act;* that in the event the Secretary acts to establish a tolerance for residues on processed foods under section 406 actions for adulteration will be taken under section 402(a)(2) but *if the Secretary has not acted under section 406 any action for adulteration because of excessive pesticide residue in the processed food will still be taken under section 402(a)(1)* [21 U.S.C. 342(a)(1)]. This understanding of the canning industry is, we are advised, shared by Dr. Miller [*i.e.*, Representative Miller, the sponsor of the House bill], by the FDA, and by all others interested in this legislation.

See also *Residues of Pesticide Chemicals: Hearing on S. 2868 and H.R. 7125 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 83d Cong., 2d Sess. 93 (1954) (NCA letter to the Senate committee chairman to the same effect).

cannot camouflage the fact that the two circuits interpret the statutory provisions in ways that are fundamentally irreconcilable. While the D.C. Circuit held (App., *infra,* 2a) that "the FDA may not proceed by means of action levels rather than tolerances," the Fifth Circuit in *Boston Farm Center* expressly recognized (590 F.2d at 151) that the FDA had the discretion to follow either procedure. Moreover, it would be patently inconsistent to hold, as the court below did, that FDA action levels are unlawful substitutes for formal tolerances while at the same time to hold, as the Fifth Circuit did in *Boston Farm Center,* that the distribution of grain may be enjoined based upon "considerable deference" to the FDA's action level. Surely the distributor in *Boston Farm Center,* who stood to suffer considerable economic loss, had at least an equal claim to the protection of the formal tolerance procedures as did respondents in this case, whose claim of injury is far more speculative.

The court of appeals' interpretation of Section 346 is also inconsistent with the Seventh Circuit's interpretation of 21 U.S.C. 346a(b), which deals with the promulgation of regulations applicable to pesticide residues on raw agricultural products and contains the same critical phrase as Section 346. Section 346a(b) provides in pertinent part (emphasis added):

> *The Administrator [of EPA] shall promulgate regulations establishing tolerances* with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, *to the extent necessary to protect the public health.*

In *United States* v. *Goodman,* 486 F.2d 847, 854 (7th Cir. 1973), the court construed this provision to allow EPA the discretion to decide whether to set a tolerance:

> The language of Section 346a(b) provides for promulgation of regulations establishing tolerances "to the extent necessary to protect the public health." EPA has determined that a regulation for DDT in raw fish is not necessary at this time. In fact, they have refrained from promulgating such a regulation because DDT levels in the environment are in a state of flux, a state partially induced by their other control activities concerning DDT.



This interpretation supports the FDA's understanding of the language in Section 346 and clashes sharply with that of the D.C. Circuit in this case.[6]

To be sure, *Boston Farm Center* and *Goodman* did not arise in precisely the same posture as the present case. If there were a significant possibility that such a case might arise in a court of appeals other than the D.C. Circuit, it might be appropriate for this Court to defer review until that occurred. But the likelihood that any circuit other than the D.C. Circuit will confront the legal issue decided below seems remote. Any party seeking to compel the FDA to issue a formal regulation may bring suit in the District of Columbia (see 5 U.S.C. 703), and in view of the decision below such a party is almost certain to make that choice of venue.

3. Unless reversed, the court of appeals' decision will have significant adverse practical consequences. In the first place, it will impose a severe administrative burden on the FDA and require the reallocation of scarce resources from activities of far greater value in protecting public health. As Congress has observed, the formal rulemaking procedures set out in 21 U.S.C. 371 are "cumbersome, time-consuming, and impracticable." S. Rep. 1635, *supra,*

---

[6] While the language of Sections 346 and 346a is similar in the respect noted above, the overall scheme for regulating pesticide chemicals in or on agricultural commodities differs significantly from the statutory scheme governing other added, deleterious or poisonous substances. Accordingly, we do not believe that the decision of the court of appeals applies to action levels for pesticides.

at 2; H.R. Rep. 1385, *supra,* at 2.[7] Yet the D.C. Circuit's decision would mandate such proceedings for numerous substances. The FDA currently has 21 informal action levels for eight substances that could be regarded as within the scope of Section 346,[8] and the decision below, at the least, would seem to require that each of these be replaced by a formal tolerance. Moreover, the logic of the court of appeals' decision is not limited to those substances for which an action level has been set but rather extends to all added, unavoidable poisonous or deleterious substances in food.

Once formal tolerances are set, they may hamper the FDA's ability to respond quickly to new scientific findings or improvements in manufacturing processes that make it practicable to reduce the level of adulterants. See 21 C.F.R. 509.6(b)(3). If a formal tolerance is in effect, a food that does not exceed the tolerance is automatically deemed to be safe and not adulterated under Sections 342(a)(2) and 346. In addition, Section 346 provides that

---

[7] This is graphically illustrated by the adoption of formal tolerances for polychlorinated biphenyls (PCBs) in paper materials used in packaging foods. In March 1972, the FDA proposed to establish formal tolerances for PCBs in food and paper food-packaging materials. 37 Fed. Reg. 5705. In July 1973, the FDA published a final rule based on the proposal. 38 Fed. Reg. 18096. At the request of several paper industry firms a public hearing was granted. 40 Fed. Reg. 11563 (1973). Subsequently, the FDA's Bureau of Foods and the industry parties reached a proposed settlement agreement, which was submitted for the Commissioner's approval in November 1978. After further proceedings, a revised settlement agreement was announced in the *Federal Register* in August 1983. 48 Fed. Reg. 37020. Thus, the promulgation of a formal tolerance—where there was an objection but no full trial-type hearing—took more than a decade to complete.

[8] FDA action levels to which Section 346 could apply are: aflatoxin, cadmium, crotolaria seeds, mercury, nitrosodimethylamine (NDMA), paralytic shellfish toxin, polybrominated biphenyls (PBBs), and plychlorinated biphenyls (PCBs).



the food may not then be considered to be adulterated within the meaning of Section 342(a)(1)—even if the government could prove in court that the food may be "injurious to health." Thus, if a formal tolerance is issued and it is later discovered that the limit is too high, foods that satisfy the formal tolerance but that may in fact be unsafe according to the latest scientific studies will still be considered safe and unadulterated under the FDCA until the lengthy process of issuing a new, lower tolerance can be completed.[9]

Finally, the reasoning of the court of appeals casts a cloud over the legality of much of the nation's food supply. As previously noted, one of the two bases for the decision below was the court's mistaken belief that unless a formal tolerance has been issued any food containing an added, unavoidable poisonous or deleterious substance must be considered to be adulterated. Since much of the food supply now contains such substances (albeit in safe amounts), the obvious implication of the court's reasoning is that this food is "adulterated" within the meaning of 21 U.S.C. 331 and that persons responsible for growing, processing, or distributing it are subject to injunction (21 U.S.C. 332), seizure of the food (21 U.S.C. 334), or even criminal penalties (21 U.S.C. 333). For those potentially affected, it is cold comfort that the court's pronouncement

---

[9] This, too, is illustrated by the FDA's experience with the formal PCB tolerances. Based on newly obtained toxicological data, the FDA in April 1977 proposed to lower the existing tolerance for residues of PCBs in fish, shellfish, and several other classes of food. 42 Fed. Reg. 14487. The final rule was promulgated in 1979. 44 Fed. Reg. 38330. At the request of a fishing industry trade association, a hearing was held in May 1981, and the FDA issued its decision in March 1982. 47 Fed. Reg. 10079. After the agency invited the submission of other relevant materials (*ibid.*), the final decision was issued in May 1984. 49 Fed. Reg. 21514. Accordingly, the entire process of lowering the tolerance for PCBs in fish and shellfish took seven years, although a comparable amendment of an action level probably could have been effected in a relatively brief period.

was dictum and that the government would exercise its enforcement discretion in a fair and reasonable manner. See 21 U.S.C. 336; *Heckler* v. *Chaney,* No. 83-1878 (Mar. 20, 1985). If the court of appeals' decision is allowed to stand, one of two things must happen. Either there must be a cessation of the production and shipment of all foods containing any amount of any added poisonous or deleterious substance, or all segments of the food industry must act in apparent violation of the FDCA until the lengthy process of issuing formal tolerances is completed. We assume that the latter course would be followed in the absence of congressional action, but we do not believe that the agency and the food industry should be compelled to operate under such conditions.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

CHARLES FRIED
*Acting Solicitor General*
RICHARD K. WILLARD
*Acting Assistant Attorney General*
KENNETH S. GELLER
*Deputy Solicitor General*
SAMUEL A. ALITO, JR.
*Assistant to the Solicitor General*
LEONARD SCHAITMAN
MARLEIGH D. DOVER
*Attorneys*

THOMAS SCARLETT
*Chief Counsel*
*Food and Drug Administration*

OCTOBER 1985

## APPENDIX A

# United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

(Civil Action No. 80-03110)

COMMUNITY NUTRITION INSTITUTE, ET AL.,
APPELLANTS

*v.*

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Argued January 25, 1985
Decided March 26, 1985

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* STARR.

STARR, *Circuit Judge*: This case presents a challenge to the Food and Drug Administration's regulation of corn adulterated by the presence of aflatoxin. Aflatoxins are by-products of certain common molds that grow on various crops, including corn. The Food and Drug Administration ("FDA" or "agency") permits the shipment of corn containing aflatoxin below an informally adopted "action level." The agency has from time to time granted exemptions to its prescribed action level; moreover, the FDA has permitted blending of adulterated and unadulterated corn to obtain a mixture which the agency believed safe for use as animal feed.

Plaintiffs-appellants, two public interest groups—Community Nutrition Institute and Public Citizen Litigation Group—and an individual consumer (jointly referred to as "CNI"), brought suit in federal district court to require the FDA to adopt, by way of notice-and-comment rulemaking, formal aflatoxin levels or "tolerances," as opposed to informally implemented action levels.[1] Alternatively, CNI argued that, if action levels rather than formally adopted tolerances were permitted, their adoption or amendment and the grant of any exemptions must be treated as rulemakings subject to the procedural requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553 (1982). Finally, CNI argued that the regulations permitting blending of adulterated and unadulterated corn were contrary to law.

The District Court granted summary judgment in favor of FDA on all three issues. We now reverse with respect to the first issue and hold that, under the plain meaning of the statute, the FDA may not proceed by means of action levels rather than tolerances. By virtue of that disposition, the second issue with respect to the procedures to be employed by the agency in adopting action levels is rendered moot. As to the third issue, the blending of adulterated and unadulterated corn, we vacate that portion of the District Court's judgment and remand for further consideration in light of our holding with respect to the FDA's statutory obligation to promulgate regulations setting forth formal tolerances.

---

[1] Standing was not contested below or on appeal. It is apparently conceded under the broad grant of standing found in the relevant sections of the Food, Drug and Cosmetics Act and the Administrative Procedure Act. *See* 21 U.S.C. § 371(f)(1) (1982); 5 U.S.C. § 702 (1982). *Compare Block* v. *Community Nutrition Institute*, 104 S. Ct. 2450, 2454-56 (1984) (5 U.S.C. § 702 review is unavailable when the statute relevant to the action precludes review by the class to which plaintiff belongs).



## I

Aflatoxins cause liver damage and exhibit carcinogenic properties in animals; evidence also exists suggesting that their ingestion may cause liver cancer in humans. It is thus undisputed that aflatoxin is a "poisonous or deleterious substance" within the meaning of section 402 of the Food, Drug and Cosmetics Act, 21 U.S.C. § 342 (1982) ("the Act"). Furthermore, since aflatoxin is not an inherent constituent of corn, but results from an environmental or agricultural contaminant,[2] it must be considered an "added" poisonous or deleterious substance within the meaning of the statute.[3]

Since aflatoxin is an "added" substance, it comes within the scope of 21 U.S.C. § 342(a)(2)(A), which provides that "[a] food shall be deemed to be adulterated— . . . if it bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 346 of this title. . . ." Section 346 in turn provides:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe . . . ; *but when such substance is so required*

---

[2] Weather conditions, insect damage and possibly other factors as well may create conditions that may foster the growth of the molds that produce aflatoxin. *See* Appellee's Brief at 5 n.2.

[3] A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination. . . . An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance.* * * *
21 C.F.R. §§ 509.4(c), (d) (1984).

*or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health,* and any quantity exceeding the limits so fixed shall also be deemed to be unsafe. . . . While such a regulation is in effect limiting the quantity of such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated. . . . In determining the quantity of such added substance to be tolerated . . . the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided . . . and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

21 U.S.C. § 346 (emphasis added).

Not only is it undisputed that aflatoxin is "poisonous or deleterious" and that it is an "added" substance, but the Secretary also admits facts, *see* Appellee's Brief at 4, sufficient to conclude that the presence of aflatoxin in food may render such consumables injurious to health. Hence, section 342 would, except for the saving grace of section 346, define any aflatoxin-tainted corn to be adulterated, and such corn would therefore be banned from interstate commerce, *see* 21 U.S.C. § 331(a). Nonetheless, since it is also undisputed that aflatoxin is unavoidable, occurring as it does in nature, section 346 may still allow for its interstate transportation. The question before us is what, if any, procedures the Secretary or her delegate, the Commissioner of FDA, is required to follow in invoking the savings provisions of section 346.

The principal point of contention between the parties is over the meaning of that portion of the statutory provision, highlighted in the text above, which reads: "[B]ut



when such substance . . . cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health. . . ." Emphasizing the word "shall," CNI argues that the Secretary is statutorily obligated to issue regulations embodying a tolerance for the substance before the product may lawfully be introduced into interstate commerce. The Commissioner, on the other hand, maintains that this provision merely *authorizes* FDA to issue tolerances but that the agency may, alternatively, elect to proceed by means of informal action levels indicating the levels of contamination below which the FDA will exercise its enforcement discretion, provided under 21 U.S.C. § 336,[4] not to take action. We are thus required to divine the intent of Congress with respect to FDA's authority in this respect under the Act.

## II

In questions of statutory construction, our initial inquiry must be, as this court has recently stated, to "determine whether Congress 'has directly spoken to the precise question at issue.'" *General Motors Corp.* v. *Ruckelshaus,* 742 F.2d 1561, 1566 (D.C. Cir. 1984) (*en banc*) (quoting *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 104 S. Ct. 2778, 2781, (1984)). In that process, "reviewing courts . . . must not 'rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.'" *Bureau of Alcohol, Tobacco and Firearms* v.

---

[4] "Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336.

*Federal Labor Relations Authority*, 104 S. Ct. 439, 444 (1983) (quoting *NLRB* v. *Brown*, 380 U.S. 278, 291-92 (1965)). *See also Chevron, supra*, 104 S. Ct. at 2781-82, ("If the intent of Congress is clear . . . the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

After careful review, we find that Congress has spoken on the issue in question and that the intent of Congress is abundantly clear in requiring the formal issuance of tolerances, rather than permitting agency reliance solely on informal action levels. The interpretation accorded the Act by the FDA flies in the teeth of Congress' clear intent and, under long established principles of administrative law, must therefore be rejected.

A

Our analysis begins, of course, by turning to the language of the statute itself. *See, e.g., Consumer Product Safety Comm'n* v. *GTE Sylvania,*, 447 U.S. 102, 108 (1980) ("the starting point for interpreting a statute is the language of the statute itself"); *Reiter* v. *Sonotone Corp.*, 442 U.S. 330, 337 (1979) ("our starting point must be the language employed by Congress"); *Center for Auto Safety* v. *Ruckelshaus*, 747 F.2d 1, 3 (D.C. Cir. 1984) (same, quoting *Reiter*). The presence of the critical word "shall" plainly suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated. The FDA's response to this common-sense reading is to point to the statutory phrase, "to such extent as [the Secretary] finds necessary for the protection of public health." The FDA contends that this phrase modifies the word "shall," and that the agency's decision to proceed by action levels rather than tolerances properly lies within the FDA's broad discretion. Under this view, the Commissioner may simply conclude that establishing a tolerance is not



necessary for the protection of public health and, so the FDA argues, the agency may thus proceed by informal action levels.

It is, however, clear from the structure of the sentence at issue here that the phrase relied upon by the Secretary simply does not modify the pivotal word "shall." Rather, the qualifying phrase serves an entirely different office; it explains the standard that the Secretary is to employ in setting the tolerance. The Secretary must promulgate regulations embodying tolerances, but the level above which food is taken to be adulterated is to be that which the agency "finds necessary for the protection of public health."

This conclusion is supported by the overall structure of the statutory section in question. Section 346 first provides any poisonous or deleterious substances added to any food are deemed to be unsafe; however, an exemption is also built in to the opening provisions of section 346. Specifically, the statute exempts foods containing *unavoidable* adulterants. But the language does not stop there; the provision then states that the Secretary "shall" promulgate regulations (*i.e.*, set tolerances) limiting the quantity of the substance. Further, the section provides that, when a regulation establishing a tolerance is in effect, such food will not be considered adulterated. Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce.

In arguing, quite correctly, that language must be treated in context, the FDA urges us to look to section 336 of the Act. *See supra* note 4. There, the agency divines a grant of discretion not to establish tolerances yet to allow the shipment of corn below the prescribed action level. The FDA argues that this section thus

allows it to issue action levels standardizing the exercise of prosecutorial discretion.

The language of section 336 does lend modest support to FDA's position: "Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunctive proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. However, the prosecutorial discretion for which the FDA argues here does not appear to be that envisioned by this particular provision of the statute. Section 336, in effect, requires the Secretary to issue a written notice or warning in instances in which the agency decides not to take some form of enforcement action. That section does not, however, allow the shipment of aflatoxin-tainted corn without the establishment of a tolerance. Rather, it clearly vests the agency with discretion to decline to prosecute someone who exceeds the tolerance, even if the tolerance is zero, if the FDA determines that a written notice or warning will be adequate to protect the public interest.

B

The language of the statute clearly requires the issuance of formal regulations or tolerances.[5] While, as both

[5] FDA does not, or could it, argue that adhering to the plain language of the statute would lead to an irrational result or have effects destructive of the policy considerations that informed the enactment of the legislation in the first instance. *Compare, e.g., Commissioner* v. *Brown*, 380 U.S. 563, 571 (1965) (courts have some scope to reject a common or literal meaning " 'where acceptance of that meaning would lead to absurd results . . . or would thwart the obvious purpose of the statute' ") (quoting *Helvering* v. *Hammel*, 311 U.S. 504, 510-11 (1941)). Instead, the agency argues that requiring full-blown notice-and-comment procedures would be highly burdensome and unduly time-consuming for a regulatory



parties invite us to do, we will consider the legislative history, "[a]bsent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Product Safety Commission* v. *GTE Sylvania, Inc., supra,* 447 U.S. at 108. Upon analysis, we find little guidance in the legislative history and certainly not the clear intention necessary to counter the expression of clear language of the statute.

As is usually the case, both sides have emerged from their respective digs into the history of this legislation pointing to historical items supportive of their respective theories. CNI claims support for its position from the fact that, while the Senate version of the bill *authorized* the Secretary to issue tolerances, a subcommittee of the House Interstate and Foreign Commerce Committee changed the language to provide that the Secretary *shall* promulgate tolerances. FDA does not quarrel with this find unearthed by CNI, but asserts that no conclusion of moment should be drawn from the fact of this change. Indeed, as is not infrequently the case in the precincts of legislative history, the subcommittee did not explain, in the committee print, its reasons, if any, for modifying the language in this respect. *See House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., Committee Print No. 3* (August 19, 1937), *reprinted in* 81 Cong. Rec. (Appendix) 2341, 2344 (August 21, 1937).

entity which is plagued with limited resources. We are not unmindful of those concerns, but it is simply not our place to do anything about them. Those concerns, rather, are best addressed within the political branches, not the courts. Our task is to interpret the law. We cannot carry out that function in a principled manner by reading the statute with a perspective driven by the exigencies of agency resources or the lack thereof.

For its part, the FDA observes that, when the full House Commerce Committee reported on the Act, the section in question was described in the following way: "This subsection first prohibits the unnecessary addition of poisons. Where such additions are necessary, the establishment of tolerances is *authorized,* based upon the practical necessities for the use of poisonous substances." *See* H.R. Rep. No. 2139, 75th Cong., 3d Sess. at 6 (1938) (emphasis added). Thus, agency "authority" to issue tolerances, as opposed to a statutory *obligation* to do so, is seen by FDA as having been provided for by the Act.

Where we are left at the end of the day with respect to the House Report that the House Report is, at bottom, consistent with either side's position. To be sure, as FDA emphasizes, the Report does state that the Secretary has *authority* to promulgate regulations, and this formulation indeed suggests a grant of discretionary authority. However, when this portion is read in context—as FDA earnestly urges us to do in parsing the statutory language itself—the Report in pertinent part first observes the existence of a ban on adulterated foods and then goes on to say that tolerances are authorized. The indication is that, without the tolerance, shipment of the food would not be allowed. *See id.* at 2 ("The addition of poisons to foods is prohibited except where such addition is necessary or cannot be avoided; *and in such cases tolerances are provided limiting the amount of added poisons* to the extent necessary to safeguard the public health.") (emphasis added). In a word, while the agency has authority to issue tolerances, the Report does not say that it has authority to allow the shipment of adulterated food without issuing such tolerances.

The language of the earlier Senate Report accompanying S. 5, which was the bill considered by the committee in House Report No. 2139, is infected with the



same ambiguity. It prohibits poisonous or deleterious substances and then authorizes the establishment of tolerances. In contrast to the House bill, however, this earlier Senate bill would have established a Presidentially-appointed committee to advise the Secretary in setting tolerances. That measure also provided that the Committee's recommendation would be the subject of a hearing, after which the regulation could be promulgated. The approval of a majority of the committee was required for any such regulation. *See* S. Rep. No. 646, 74th Cong., 1st Sess. 3 (1935). Since this provision changed before enactment, the Report of course is not entitled to much weight. It does, however, indicate that the Senate had expected a far more elaborate procedure than that argued for here by FDA.

C

Beyond these nooks and crannies of legislative history, the FDA argues that ample case law on the very question before us supports the agency's position. We find, however, that the authorities invoked by FDA are decidedly inapposite. For example, the FDA relies upon *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), as support for its position that the agency may, but is not required to, issue tolerances. That case indeed observes that "[i]n implementing the Act, the FDA either may adopt formal regulations . . . or may litigate alleged violations on a case-by-case basis." *Id.* at 151 (citation omitted) (noting also the discretion granted by section 336). However, *Boston Farm Center* is, in respect of the issue before us, a horse of an entirely different color, namely a suit by the United States to halt distribution of aflatoxin-tainted corn. Boston Farm Center, an enterprise situated not in New England but in Georgia, claimed in defending against an enforcement action that FDA could not halt

distribution without first having issued a tolerance. Since evidence existed that aflatoxin was an adulterant and that at the level there present the tainted corn was unsafe, the court held that the FDA could take action in such an individual case, without establishing a rule for all cases. The agency's authority at issue there was the entirely different one of power to enjoin shipment.

The same is true of *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980), another authority invoked by the Commissioner. In that case, the district court ruled that the item in question there (swordfish) was safe but also found without merit the defendant's contention that the FDA was required to establish a tolerance. *See id.* at 1153 n.2. Here again, it was the United States taking enforcement action, with the defendant claiming that its product could not be prohibited without the FDA's first establishing a tolerance. And, as in *Boston Farm Center*, the ability of the United States to prohibit shipment of food without having first established a tolerance simply does not, in our view, speak to the agency's refusal to establish a tolerance while permitting shipment.

*United States* v. *Goodman*, 353 F. Supp. 250 (E.D. Wisc. 1972), *aff'd*, 486 F.2d 847 (7th Cir. 1973), and *aff'd sub nom. U.S.* v. *Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied sub nom. Vita Food Products* v. *U.S.*, 420 U.S. 945 (1975), spoke more directly to this point. As in the two cases already discussed, a defendant-shipper had claimed that the FDA could not proceed against him without first establishing a tolerance. The court stated:

> [A]lthough the provisions of subsection (b) [of section 346a, a similarly worded section for the establishment of tolerances,] would seem, facially, to suggest a duty to promulgate regulations that con-



> tain tolerances, I am persuaded that the total statutory scheme contemplates a judicial obligation to enjoin the distribution of unsafe foods even in the absence of a formally promulgated regulation.

*Id.* at 251. The court thus recognized the narrowly limited scope of the question it was deciding and entered an injunction against the challenged shipment notwithstanding the absence of established tolerances. The court said nothing as to permission to ship without the establishment of tolerances.

Other cases cited by the FDA likewise involved these familiar refrains by defendants in enforcement proceedings that they could not be enjoined from shipping unadulterated food absent the FDA's prior establishment of tolerances. The courts in those cases also held that case-by-case adjudication was allowable, but they did not speak to the precise issue in contention here. *See United States* v. *General Foods Corp.*, 446 F. Supp. 740, 745 (N.D. N.Y.) (also noting that "Congress has apparently mandated that the F.D.A. establish tolerances for poisonous or deleterious substances which are required or unavoidable in the production of food, such regulations relating to adulteration under [21 U.S.C. § 342(a)(2)], see 21 U.S.C. § 346" but that there was no such requirement under the subsection at issue in that case), *aff'd*, 591 F.2d 1332 (2d Cir. 1978); *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare*, 236 F.2d 866 (2d Cir. 1956) (defendant could not require tolerance before action taken against it).[6]

---

[6] The FDA finds further support for the proposition that "shall" does not mean "required" in *United States* v. *Dotterweich*, 320 U.S. 277 (1943), and *United States* v. *Morgan*, 222 U.S. 274 (1911). However, an examination of the cases shows that they fail to support the FDA's position here. In *Dotterweich*, the defendant invoked section 305 of the Act, which read: "Before any violation of

The State of South Carolina, as *amicus curiae* in support of the FDA, presents a separate argument based upon two Supreme Court cases. In *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), the Court had held that, under the 1906 version of the Act, the simple existence of a deleterious or poisonous substance did not make a product adulterated. Rather, a requirement existed that the substance must be present in such quantity that it might render the product injurious to health. In *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 161 (1958), the Court held that the rule in *Lexington Mill* still applied to section 402(a)(1) of the 1938 Act, 21 U.S.C. § 342(a)(1). From these two cases, South Carolina concludes that to interpret the law so as to require the existence of tolerances—before

---

this chapter is reported by the Administrator to any United States Attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings." *See United States* v. *Buffalo Pharmacal Co.*, 131 F.2d 500, 502 n.3 (2d Cir. 1942), *rev'd sub nom. United States* v. *Dotterweich*, 320 U.S. 277 (1943). The Supreme Court "agree[d] with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution." *Dotterweich, supra*, 320 U.S. at 279. Turning to the Court of Appeals opinion in that case, we find the appellate court agreeing with the district court's ruling that "the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings." *Buffalo Pharmacal, supra*, 131 F.2d at 502. The case simply does not stand for the proposition that "shall" can be read as "may." To the contrary, "shall" indicated to a singularly distinguished panel of the Second Circuit (L. Hand, Swan, and Chase, JJ.) nothing less than an "administrative *direction*." The court merely concluded that failure to follow that direction did not result in a loss of criminal jurisdiction. *Morgan*, based on the 1906 version of the Act, similarly held that a provision that "notice shall be given" was not a jurisdictional requirement.



shipment is allowed—would be to bar shipment of food containing *de minimus* or harmless traces of poisonous or deleterious substances in violation of *Lexington Mill*.

However, the 1906 and 1938 Acts differ significantly in this area. While the 1906 Act contained a section similar to section 402(a)(1) of the 1938 Act, 21 U.S.C. § 342(a)(1), it did not contain a section equivalent to section 402(a)(2) of the 1938 Act, 21 U.S.C. § 342(a)(2). *See* 34 Stat. 768, 769-70 (1906). It is the latter provision, 21 U.S.C. § 342(a)(2)(A), that defines as "adulterated" food which is unsafe within the meaning of 21 U.S.C. § 346; *Lexington Mill* and *Flemming* thus do not speak to the issue at hand. Any relevance those cases might have is further diminished by the fact that they likewise involved enforcement actions by the United States against producers or distributors; they do not address the FDA's authority *vel non* to allow shipment of adulterated foods without the establishment of tolerances.

## III

Since we have concluded that the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) or unsafe for purposes of 21 U.S.C. § 342(a)(2)(A), we need not consider the second issue on appeal. Appellants' argument that the establishment of action levels, and the amendment of and grant of exemptions thereto, were rulemakings within the meaning of the APA is rendered moot by our determination as set forth above.

Finally, appellants maintained below that the FDA's approval of blending of aflatoxin-contaminated corn was likewise violative of the Act. The District Court rejected this challenge on the ground that the agency

could properly proceed by action levels and could then grant exemptions to these levels. Inasmuch as the District Court's rationale in this respect was premised upon a statutory interpretation that we are constrained to conclude was in error, we vacate as well that portion of the District Court's judgment and remand for further consideration in light of the duty incumbent on the FDA to promulgate regulations setting forth formal tolerances, as well as appellants' further specific arguments advanced in this respect.

*It is so ordered.*



**APPENDIX B**

# United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

---

No. 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
APPELLANTS

*v.*

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

---

[Filed May 1, 1985]

---

**ORDER**

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

It is ORDERED, by the Court, *sua sponte*, that the Opinion for the Court filed by Circuit Judge Starr on March 26, 1985 be, and hereby is, amended as follows:

Page 2, paragraph 2 of text, lines 2-3, eliminate the words "Litigation Group" so that the second public interest group is identified as "Public Citizen".

Per Curiam
For The Court

GEORGE A. FISHER
*Clerk*

APPENDIX C

# United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

---

No. 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
AND LAURA A. ROGERS

*v.*

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

---

[Filed May 23, 1985]

---

**ORDER**

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

Upon consideration of appellee's petition for rehearing, it is

ORDERED, by the Court, that the petition is denied.

Per Curiam
FOR THE COURT

GEORGE A. FISHER
*Clerk*

BY: /s/ ROBERT A. BONNER
ROBERT A. BONNER
*Chief Deputy Clerk*



APPENDIX D

# United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

---

No 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
AND LAURA A. ROGERS

*v.*

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

---

[Filed May 23, 1985]

---

**ORDER**

Before: ROBINSON, *Chief Judge,* WRIGHT, TAMM, WALD, MIKVA, EDWARDS, GINSBURG, BORK, SCALIA, and STARR, *Circuit Judges.*

Appellee's suggestion for rehearing *en banc* has been circulated to the full Court and no member has requested the taking of a vote thereon. Upon consideration of the foregoing, it is

ORDERED, by the Court *en banc*, that the suggestion is denied.

Per Curiam
FOR THE COURT

GEORGE A. FISHER
*Clerk*

BY: /s/ ROBERT A. BONNER
ROBERT A. BONNER
*Chief Deputy Clerk*

APPENDIX E

# United States District Court

FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

*v.*

MARK NOVITCH, ACTING COMMISSIONER
OF FOOD AND DRUGS, DEFENDANT

[Filed Feb. 14, 1984]

**ORDER**

Upon consideration of the motion of plaintiffs for summary judgment and the motion of defendant to dismiss or, in the alternative, for summary judgment, the memoranda of law in support and opposition, the argument of counsel, the entire record herein, and consistent with the Memorandum Opinion, it is this 14th day of February, 1984,

ORDERED that the motion of plaintiffs for summary judgment be, and hereby is, denied; and it is further

ORDERED that the motion of defendant to dismiss be, and hereby is, denied; and it is further

ORDERED that the motion of defendant for summary judgment be, and hereby is, granted; and it is further

ORDERED that this case be, and hereby is, dismissed with prejudice.

/s/ NORMA HOLLOWAY JOHNSON
NORMA HOLLOWAY JOHNSON
*United States District Judge*



# United States District Court

FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFF,

*v.*

MARK NOVITCH, ACTING COMMISSIONER
OF FOOD AND DRUGS, DEFENDANT

[Feb. 17, 1984]

**MEMORANDUM OPINION**

This case involves the toxic substance aflatoxin which is produced by mold on some agricultural products. Aflatoxin has been shown to be a liver carcinogen in laboratory animals, and studies suggest that it may be associated with primary liver cancer in humans. Plaintiffs, Community Nutritition Institute (CNI), Public Citizen (PC), Linda Bardot, and Laura Rogers, seek declaratory and injunctive relief against the Food and Drug Administration (FDA) and challenge the FDA's method of regulating the interstate shipment of corn adulterated with aflatoxin.

This matter is before the Court on cross-motions for summary judgment and the motion of defendant to dismiss. Upon consideration of these motions, the argument of counsel, and the entire record herein, and for the reasons stated below, the Court grants the motion of defendant for summary judgment.

**BACKGROUND**

The shipment into interstate commerce of adulterated food is expressly prohibited under section 301 of the Food, Drug and Cosmetic Act (Act), 21 U.S.C. § 331.

Section 402 of the Act defines "adulterated food" as, among other things, food which "bears or contains any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. § 342 (section 402(a)(1)). To enforce this section and prevent the interstate shipment of food containing poisonous substances which may render the food injurious to health, the FDA sets "action levels." These "actior levels" represent the agency's judgment as to the level of contamination which can be permitted before the FDA is prepared to recommend regulatory action under the Act.* Action levels, according to defendant, are established as "in-house prosecutorial guidelines" to implement the adulteration provisions of the statute. At present, action levels are not subject to notice and comment rulemaking procedures under the Administrative Procedure Act (APA). Rather, upon adoption of an action level for a poisonous and deleterious substance, the FDA publishes a notice in the Federal Register announcing the new action level and the availability of all the relevant data. 42 Fed. Reg. 52817 (Sept. 30, 1977). The notice invites public comment on the action level. *Id.* Since 1969, the action level for aflatoxin in animal feed and human food has been 20 parts per billion (ppb). Any product with more than 20 ppb aflatoxin is subject to regulat ry action by the FDA.

The Act also provides that a food is adulterated if it "bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 406. . . ." 21 U.S.C. § 331 (section 402(a)(2)). Section 406 states that if an added poisonous

* Because all FDA initiated enforcement actions are brought by and in the name of the United States, the FDA must recommend each anticipated action to the Department of Justice. 21 U.S.C. § 337. *See Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598-99 (1950).



substance is required in the production of the food or if it cannot be avoided by good manufacturing practices:

> [t]he Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a).

This section provides for the establishment of formal tolerance levels which, contrary to action levels, are subject to rulemaking procedures of the APA. No formal tolerance level has been set for corn contaminated with aflatoxin.*

Implementation of the adulteration provisions of the Act is an issue before the Court. In 1974 the FDA considered how it might implement the adulteration provisions of the statute by proposing criteria governing when the agency might establish a formal tolerance or an action level and criteria governing exemptions from regulatory action. *See* Notice of Proposed Rulemaking; Poisonous and Deleterious Substances in Food, 39 Fed. Reg. 42743 (Dec. 6, 1974). In that 1974 notice of proposed rulemaking the FDA also made clear its position that section 406 permits, but does not require, the agency to establish formal tolerances for poisonous substances added to food. 39 Fed. Reg. at 42743, 42744, 42745. Further, the FDA made several other proposals in the 1974 notice that are relevant to this case. First, the FDA proposed the use of informal notice and comment

* Aflatoxin is a by-product of the growth of certain molds on crops and, as such, is an "added" poisonous substance. Further, on some susceptible products like corn, aflatoxin cannot be avoided by good manufacturing practices. Therefore, section 406 is applicable to aflatoxin-contaminated corn.

procedures when setting action levels. Second, the FDA proposed that blending a food containing a poisonous or deleterious substance above the tolerance or action level with another lot of food be prohibited. Third, the FDA proposed that any exemptions from regulatory action for food unlawfully contaminated with a poisonous or deleterious substance be published in the Federal Register with time for public comment "whenever feasible" and "in the event there were not time for public comment, the exemption could be issued as a final determination rather than as a proposal."

A final regulation was not promulgated until September 1977. Although the provisions of the 1974 Notice of Proposed Rulemaking contained a prohibition against blending and recommended the use of informal notice and comment procedures when setting action levels, such were deleted from the final regulation and have never been adopted by the FDA. 42 Fed. Reg. 52814 and 52817. The final regulation retained the proposed criteria governing when the FDA would use formal tolerances and when it would use action levels.* It also retained the proposed provisions governing exemptions from regulatory action and permission to market some products contaminated with a poisonous or deleterious substance.**

---

* The provisions of the final regulation governing the use of action levels and formal tolerances are now codified in 21 C.F.R. § 109.6 (covering human food) and § 509.6 (covering animal feed).

** The provisions of the final regulation governing exemptions are codified in 21 C.F.R. § 109.8 (human food) and § 509.8 (animal feed). Section 509.8 provides in pertinent part:

> (a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:
>
> (1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption, and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.
>
> (2) Such determination is published as a notice in the Federal Register and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.



Since the final regulations were adopted, the FDA has, on two occasions granted exemptions from regulatory action pursuant to those regulations. In 1978 the FDA permitted corn containing more than 20 ppb aflatoxin to be 'blended' with less contaminated corn and permitted the final blended product to be shipped in interstate commerce. Notice of the exemption and of the availability of information supporting the FDA's decision to exempt was published in the Federal Register as 21 C.F.R. § 509.8 requires. *See* 43 Fed. Reg. 14122-23 (April 4, 1978). The 1978 exemption applied only to corn harvested in 1977 in the southeastern United States and required the approval of the FDA before the blended product could be shipped in interstate commerce. This exemption expired on January 1, 1979. No firm or individual sought to take advantage of the exemption and none of the plaintiffs submitted comments on the exemption after it was published in the Federal Register.

Again in 1980, the FDA granted a limited exemption to its general prohibition against blending contaminated products. *See* 46 Fed. Reg. 7447-49 (Jan. 23, 1981). This exemption came in response to requests from the states of North Carolina, South Carolina, and Virginia. The exemption was announced in the Federal Register in January 1981 and expired January 1982. The notification in the Federal Register solicited public comment and advised the public of the availability of the relevant information. 46 Fed. Reg. at 7447, 7449. The 1980 ex-

emption applied only to corn harvested in 1980 in the three states that solicited the exemption. Contrary to the 1978 exemption, the FDA announced that in this instance it would not recommend regulatory action against corn containing between 20 ppb and 100 ppb aflatoxin or a blended product of no more than 100 ppb aflatoxin "if, *inter alia*, the corn was used only for feeding mature, nonlactating livestock and mature poultry." 46 Fed. Reg. 7448. In all other cases the 20 ppb action level still applied. A decision by the FDA not to recommend regulatory action was, however, contingent upon state and industry compliance with plans designed to ensure that "corn containing between 20 ppb and 100 ppb aflatoxin was not diverted for uses other than as feed for the animals specified and blending of corn achieved a level of no more than 100 ppb aflatoxin." Defendant's Opposition to Plaintiff's Motion for Summary Judgment at 10.

In a letter dated October 6, 1980, plaintiff CNI urged the FDA to reconsider adopting the 1980 exemption. When plaintiffs were unsuccessful, they filed this action.

## CONTENTIONS OF THE PARTIES

Plaintiffs move this Court to grant their motion for summary judgment for the following reasons. (1) Plaintiffs assert that section 406 of the Act requires the FDA to establish formal tolerance levels for aflatoxin in corn products and that the use of informal action levels rather than formal tolerance levels is violative of the Act. (2) If a formal tolerance level is not required, plaintiffs contend that the informal action level for aflatoxin in corn and the exemptions thereto set by the FDA are subject to the rulemaking requirements of the APA and the failure of FDA to hold notice and comment proceedings violates the APA. (3) Plaintiffs further maintain



that the FDA's policy of granting exemptions to its long-standing prohibition against blending contaminated products violates the Act and the FDA's own regulations.

Defendant counters these allegations in its motion to dismiss or, in the alternative, for summary judgment by maintaining that plaintiffs fail to state a claim upon which relief can be granted and that the Court lacks subject matter jurisdiction over this action. According to defendant, the FDA is authorized by section 406 of the Act to establish a formal tolerance for aflatoxin in corn but is not required to do so. Further, defendant asserts that the action levels set by the FDA and their exemptions are statements of policy and are not rules; therefore, they are not subject to the notice and comment procedures of the APA. On the issue of blending contaminated corn, defendant argues that the FDA regulations prohibiting "blending" do not apply to the present case and that plaintiffs challenge to the 1980 and 1978 exemptions is moot. In addition, defendant contends that this Court lacks jurisdiction over the subject matter of the case because plaintiffs failed to exhaust administrative remedies and to participate in the notice and comment period following the 1974 Notice of Proposed Rulemaking.

## DISCUSSION

It is a long-standing rule of administrative law that a party must exhaust administrative remedies before seeking judicial review of its complaint. *See, e.g. Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971); *McKart* v. *United States*, 395 U.S. 185, 193 (1969). Courts are admonished to exercise jurisdiction only after the administrative agency involved has had an opportunity to hear the matter, apply its expertise, and develop a factual record of its decision. *McKart*, 395

U.S. at 194. The doctrine of exhaustion is intended to prevent unnecessary interference by the courts into the administrative process. Another purpose behind the doctrine involves the practical notion of judicial efficiency that comes into play if agency consideration of the issues could resolve the dispute and obviate the need for judicial action. *Id.* at 195. However, in instances where efforts to completely exhaust administrative remedies would be an exercise in futility, *Lodge 1858, American Federation of Government Employees* v. *Paine,* 436 F.2d 882, 896 (D.C. Cir. 1970), or where the issue involved is a "pure question of law," *Association of National Advertisers, Inc.* v. *FTC,* 627 F.2d 1151, 1157 (D.C. Cir. 1979), immediate judicial review is available. Defendant maintains that plaintiffs failed to exhaust their administrative remedies by not first presenting their claims to the FDA by petition. The Court finds that plaintiffs need not exhaust the available administrative remedy. First, plaintiffs' claim that section 406 of the Act requires the FDA to establish formal tolerances for corn products contaminated with aflatoxin is a question of law. Whether the Act affirmatively requires the FDA to take certain action is a legal question about which the agency can contribute no particular expertise. *Id.* at 1157. Second, further exhaustion of plaintiffs' challenge to the FDA's policy of not invoking notice and comment rulemaking procedures before setting action levels would not serve the purposes behind the exhaustion doctrine. This challenge does not involve disputed factual issues demanding creation of a better administrative record. *Id.* Further, the FDA has already considered these issues in its 1974 Notice of Proposed Rulemaking and the agency's position on them is clear. *National Resources Defense Council* v. *Train,* 510 F.2d 692, 703 (D.C. Cir. 1974). Finally, plaintiffs challenge the FDA's policy of permitting, in limited instances, the



blending of contaminated corn products. Plaintiffs seek a declaratory judgment from this Court that such a policy is contrary to the Act. Again, this issue was explored and considered in the 1974 Notice of Proposed Rulemaking. To require the FDA to reconsider it would be an exercise in futility. Because none of the issues raised by plaintiffs involve intricate factual determinations, the agency can bring no particular expertise to this case that has not already been expressed in prior agency action. Further exhaustion is not warranted.

Another issue raised by defendant involves the well-settled rule that those who do not participate in rulemaking proceedings before the administrative agency cannot come before the Court complaining about the regulations resulting from those proceedings. *Nader* v. *NRC,* 513 F.2d 1045, 1054-55 (D.C. Cir. 1978). In this case, defendant asserts that plaintiffs should be barred from bringing this action because the acts about which plaintiffs complaint were fully considered in the notice and comment proceedings for the 1974 Notice of Proposed Rulemaking and plaintiffs' complaint was based upon regulations or proposed regulations that arose out of the 1974 Notice of Proposed Rulemaking. While those proposed regulations were open to public comment for several years, plaintiffs did not, at that time, challenge or support any of the proposals. The Court feels compelled, however, to allow plaintiffs complaint to proceed. Mindful of the Supreme Court's view that "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review," this Court will not bar plaintiffs' claim simply because they did not participate in the general Notice of Proposed Rulemaking a decade ago. *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, 141 (1967). Fairness dictates judicial review in this instance.

Defendant's final procedural challenge to plaintiffs' complaint raises a question of mootness. Defendant maintains that plaintiffs' challenge to the grant by the

FDA of exemptions in 1978 and 1980 is moot because those exemptions have expired. Defendant argues that there is no live case or controversy with respect to those exemptions. If plaintiffs were asking this Court to declare those specific exemptions violative of the Act, defendants assertions of mootness would be correct. Rather, plaintiffs here challenge the FDA's authority to grant *any* exemptions without first complying with informal rulemaking procedures. *See* Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 16. In essence, plaintiffs are challenging the validity of the regulations upon which the FDA relies to grant exemptions. Therefore, the Court finds that the issue is not moot.

**Formal Tolerances**

Plaintiffs contend that section 406 of the Food, Drug and Cosmetic Act requires the FDA to establish, by formal rulemaking, tolerance levels for aflatoxin in corn. Further, plaintiffs argue that the FDA's use of action levels instead of tolerances in its enforcement of the adulteration provision of the Act is violative of section 406. Section 406 provides that when an added poisonous or deleterious substance is required in the production of a food or cannot be avoided by good manufacturing practices "the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe" for purposes of the adulterated food provision of the statute, section 402(a)(2)(A). Plaintiffs cite the language—"the Secretary *shall* promulgate regulations"—as authority for the proposition that formal tolerances are required. In addition, plaintiffs assert that legislative history supports their interpretation because Congress considered, but ultimately rejected, language stating that "the Secretary is authorized to promulgate regulations."



Plaintiffs' claim is without merit. The language of section 406 states that the Secretary shall promulgate regulations "to such extent as he finds necessary for the protection of public health." The FDA has interpreted this provision of the Act to mean that, in its discretion, it may decide that a tolerance is not necessary to protect the public health and therefore can decline to establish one. This interpretation has been codified in the agency's regulations at 21 C.F.R. § 509.6.

The Court recognizes that the FDA's interpretation of its own statute is entitled to "substantial deference." *United States* v. *Rutherford*, 442 U.S. 544, 553 (1979). Such deference is particularly appropriate here, where courts have consistently agreed with this interpretation. The Fifth Circuit in *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th Cir. 1979), stated that "[i]n implementing the Act, the FDA either may adopt formal regulations, 21 U.S.C. § 346 [section 406], or may litigate alleged violations on a case-by-case basis [pursuant to 21 U.S.C. § 342(a)(1) (section 402(a)(1)]." *Boston Farm Center*, like the instant case, involved aflatoxin in corn. Similarly, a district court in Florida noted that there was no merit to plaintiff's contention that section 406 required the FDA to establish a tolerance for mercury in swordfish. *United States* v. *Anderson Seafoods*, 447 F. Supp. 1151, 1153 n.2 (N.D. Fla. 1978), *aff'd*, 662 F.2d 157 (5th Cir. 1980).

Mindful of the principle that "the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong," *Red Lion Broadcasting Co.* v. *FCC*, 395 U.S. 367, 381 (1969), the Court finds that the FDA's interpretation is reasonable and that section 406 confers discre-

tionary, not mandatory, authority on the agency to establish tolerances.*

**Informal Action Levels and Exemptions**

To guide in the enforcement of section 402(a)(1) of the statute which deems a food to be adulterated "if it bears or contains any poisonous or delet[illegible]ious substance which may render it injurious to heal[illegible] the FDA sets action levels. These action levels are s[illegible]ursuant to the FDA's prosecutorial discretion to [illegible]rosecute or litigate "minor violations" of th[illegible]ct § 336 (Section 306). Plaintiffs maint[illegible]e FDA s action level for aflatoxin in corn, and the 1978 and 1980 exceptions to it, are subject to the rulemaking requirements of the APA and the failure of FDA to hold such notice and comment proceedings is violative of the APA.

Plaintiffs' contentions ignore the difference between substantive rules and general statements of policy. Unlike substantive rules, general statements of policy are not subject to informal rulemaking under the APA. 5 U.S.C. § 553(b)(A). In *Pacific Gas & Electric Co.* v. *FPC*. 506 F.2d 33, 38 (D.C. Cir. 1974), this Circuit noted that the "critical distinction between a substantive rule and a general statement of policy is the different practical effect that these two types of pronouncements have in subsequent administrative proceedings." A substantive rule establishes a standard of conduct which has the force of law, whereas a general statement of policy does not establish a "binding norm." *Id.*

Action levels are "in-house guidelines" that guide the FDA in its prosecutorial discretion in bringing about the enforcement of the Act. *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th Cir. 1979). While a

* Plaintiffs are still free to petition the agency under 21 C.F.R. § 10.25 and request that a formal tolerance be set.



court should accord deference to the FDA's action levels, they are not binding on the courts. *Id.* Moreover, action levels only represent the point at which the FDA *may* recommend regulatory action. Action levels are not substantive rules but general statements of policy. Accordingly, they are not subject to informal rulemaking procedures.

Exemptions to the 20 ppb action level for aflatoxin in corn were issued in 1978 and 1980 pursuant to FDA regulations 21 C.F.R. § 509.8. Plaintiffs argue that these exemptions are also subject to informal rulemaking procedures under the APA. Under section 509.8 the FDA must publish in the Federal Register a notice advising the public of the FDA's final action but is not required to publish a notice of proposed exemptions open to public comment. In essence, plaintiffs' complaint challenges the validity of section 509.8.*

As the Court previously noted, an agency's characterization of its own proceedings is entitled to some "weight" by the Court and "that characterization may in turn have relevance in determining the applicability of the APA rulemaking requirements." *In re FTC Corporate Patterns Report Litigation*, 432 F. Supp. 291, 304 (D.D.C. 1977), *aff'd*, 595 F.2d 685 (D.C. Cir.), *cert. denied*, 439 U.S. 958 (1978). The Court has already determined that the agency's characterization of action levels as general statements of policy and not substantive rules, is a reasonable one. General statements of policy leave the agency free to exercise its informed discretion and such statements do not impose a binding obligation on the agency. *American Bus Association* v. *United States*, 627 F.2d 525, 529 (D.C. Cir. 1980). Therefore, by granting exemptions to action levels the

* Plaintiffs must challenge the validity of the *regulations* allowing exemptions without notice and comment rulemaking. Any challenge to the specific exemptions themselves would be moot.

FDA is simply acting on its discretionary authority not to follow its own "in-house guidelines." A change in a prosecutorial guideline or general statement of policy, which is itself not subject to notice-and-comment, cannot suddenly become subject to the notice-and-comment requirement.

Finally, plaintiffs assert that the FDA's approval of the blending of aflatoxin-contaminated corn is contrary to the Act. This assertion does not square with the Court's finding that action levels are general statements of policy. The FDA retains discretion as to when to recommend an enforcement action and exemptions to action levels are within that discretion. The factors which the FDA evaluates in determining whether an exemption from an action level is appropriate are set forth in the FDA's regulations. 21 C.F.R. § 509.8. Exemptions to action levels, whether through blending or otherwise, are clearly permitted under the FDA's regulations, provided the Commissioner makes the determination that "based upon all available scientific evidence, . . . the food is safe for consumption, and . . . that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply." The Court finds no reason to disturb the agency's characterization of its own statute and accords deference to the agency's regulations.

Accordingly, the Court grants the motion of defendant for summary judgment and denies the motion of plaintiffs. An Order consistent with this Opinion has been entered.

/s/ NORMA HOLLOWAY JOHNSON
NORMA HOLLOWAY JOHNSON
*United States District Judge*

DATED: February 17, 1984



**APPENDIX F**

# United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
APPELLANTS

*v.*

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

[Filed Mar. 26, 1985]

**JUDGEMENT**

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia, and was argued by counsel. On consideration thereof, it is

ORDERED and ADJUDGED, by this Court, that the judgment of the District Court appealed from in this cause is hereby reversed in part, and vacated in part, and this case is remanded for further consideration, all in accordance with the Opinion for the Court filed herein this date.

Per Curiam
For The Court
GEORGE A. FISHER
*Clerk*

Date: March 26, 1985
Opinion for the Court filed by Circuit Judge Starr.

## APPENDIX G

### STATUTORY AND REGULATORY PROVISIONS INVOLVED

1. Section 402(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), provides:

A food shall be deemed to be adulterated—

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw



agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

2. Section 406 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346, provides:

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) (A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health,

and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

3. Section 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(e), provides:

> (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.



> (2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.
>
> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

4. 21 C.F.R. 509.6(b)-(c) provides:

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.